ATTACHMENT 53

January 13, 2022

Food and Drug Administration
Allegations of Regulatory Misconduct Team, WO66-1523
10903 New Hampshire Avenue
Silver Spring, MD 20993
Via email: CDRHDeviceAllegations@fda.hhs.gov

Re: Response from Rebotix Repair re Document Number CPT2000126

Dear Dr. Trumbore:

We write in response to your November 16, 2021, letter to Chris Gibson of Rebotix Repair ("Letter") concerning Rebotix Repair's EndoWrist services. In your letter, you request (1) any FDA clearance or approval numbers and any prior submission numbers related to Rebotix Repair's activities, and (2) the basis for Rebotix Repair's determination that its activities do not require FDA clearance or approval.

We address both of your requests in turn.

1. **Prior FDA submissions or clearances.**

As demonstrated in Section (2) below, Rebotix Repair is not engaged in remanufacturing activities. Rebotix Repair is a service entity that repairs and refurbishes EndoWrists that hospitals already own. Because it is not required to do so, Rebotix Repair has never sought FDA clearance or approval.

In contrast to Rebotix Repair, a predecessor entity Rebotix LLC intended to market and sell Rebotix-labeled EndoWrists to hospitals. Rebotix LLC submitted a 510(k) premarket notification (K143619) in December 2014. Rebotix LLC withdrew its submission on December 17, 2015. Rebotix LLC never resubmitted its application and never entered the business of selling EndoWrists.

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2. Rebotix Repair is not a remanufacturer and does not require FDA clearance.

We refer you to the attached expert reports of Joshua S. Sharlin (Exhibit 1) and J. Lawrence Stevens (Exhibit 2), which provide detailed analysis explaining the basis for Rebotix Repair's determination that it is not required to obtain FDA clearance or approval for its services.[1]

As explained in the attached expert reports, Rebotix Repair does not require FDA clearance because it does not remanufacture EndoWrists. In contrast to its predecessor, which planned to sell EndoWrists, Rebotix Repair provides repair and refurbishing services: "We do not sell any product. We only repair instruments for the hospital, with no change of ownership." Exhibit 4 (Hospital Right to Repair) at REBOTIX068471.

The FDA defines "Refurbish" as "[r]estores a medical device to the OEM's original specifications or to be 'like new' … [without] significantly chang[ing] the finished device's performance or safety specifications, or intended use." May 17, 2018, FDA Report on the Quality, Safety, and Effectiveness at p.2. This is precisely the service that Rebotix Repair offers. Hospitals hire Rebotix Repair to perform a "complete repair of the da Vinci EndoWrist" that "provides the resetting of the use counter via a replacement chip" and returns it to "original specifications." Exhibit 4 at REBOTIXO68471. And, as detailed in the accompanying expert reports, this process does not significantly change the intended use or performance and safety specifications of the EndoWrists. Exhibit 1, ¶¶46-164.

Your letter raises a concern that Rebotix Repair may be engaged in "remanufacturing" because "Rebotix's activities may be altering the intended use" of EndoWrists by "extending the number of uses." Letter at 1. The analysis in the expert reports demonstrates that extending the lives of EndoWrists (with appropriate repairs and a use counter reset) does not change the intended use of the EndoWrists. *See* Exhibit 1 (Sharlin Report), ¶¶52-71; Exhibit 2 (Stevens Report), ¶¶87-97.

The use restrictions Intuitive imposes on its EndoWrists were not set by the FDA, but were instead set by Intuitive's marketing team. Exhibit 2, ¶¶118-127. Intuitive's

[1] Mr. Sharlin's report and Mr. Stevens' report (which also adopts and incorporates by reference Mr. Sharlin's report) were prepared in connection with an antitrust lawsuit that Rebotix Repair filed against Intuitive Surgical: *Rebotix Repair LLC v. Intuitive Surgical, Inc.*, 8:20-cv-02274-VMC-TGW (M.D. Fla.). *See* Exhibit 3 (Complaint). These expert reports were recently made part of the public record.

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own 510(k) submission for its EndoWrists demonstrated to the FDA (and the FDA agreed) that the intended use of EndoWrists was the same as the intended use of traditional laparoscopic predicate devices that do not include any maximum use restrictions. Exhibit 2, ¶¶107-112; Exhibit 1, ¶63. And the defined intended use in Intuitive's EndoWrists 510(k) (which was accepted by the FDA) did not include any maximum use restrictions. Exhibit 1, ¶¶52-59; Exhibit 2, ¶¶80-92.

Indeed, because EndoWrists' intended use does not include use restrictions, Rebotix Repair's service of extending the lives of EndoWrists cannot significantly change their intended use. This is why Intuitive does not seek new 510(k) clearance each time it decides to extend the lives of its EndoWrists. Instead, in Intuitive's Non-Filing Justifications, Intuitive routinely concludes: "Extending the number of lives does not involve any changes to the intended use(s) or instrument design." Exhibit 1, ¶¶ 66-67.

We are hopeful that we have answered your questions and that the attached materials alleviate any concerns you may have. If you need any additional information, please feel free to contact us at any time.

Sincerely,

Stan Hamilton
Executive Vice President
Rebotix Repair LLC

Enclosure: Exhibits 1-4

CC: Dr. Anthony Lee, via email: Anthony.Lee1@fda.hhs.gov
Rick Lyon, via email: rick@dovel.com

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